CURRENT APPROACH TO FDA REGULATION OF ANIMAL BIOTECHNOLOGY PRODUCTS

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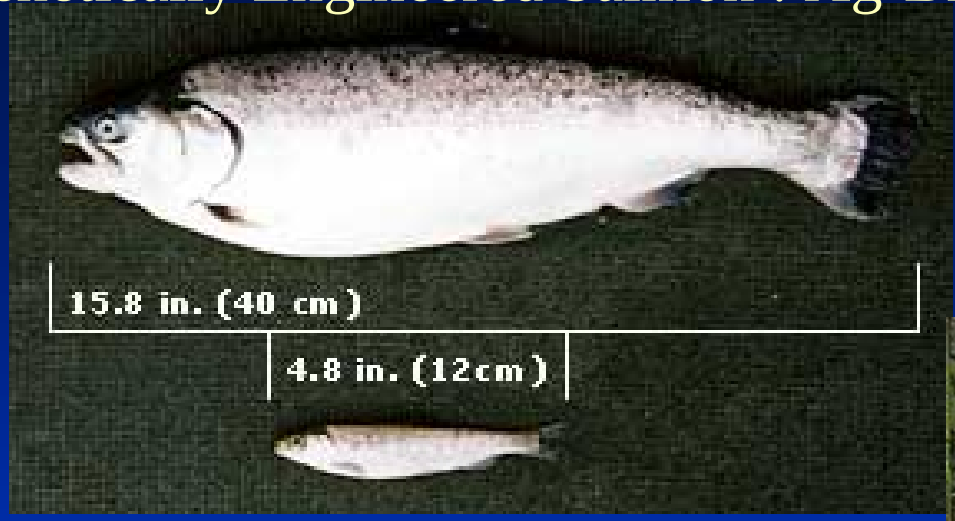
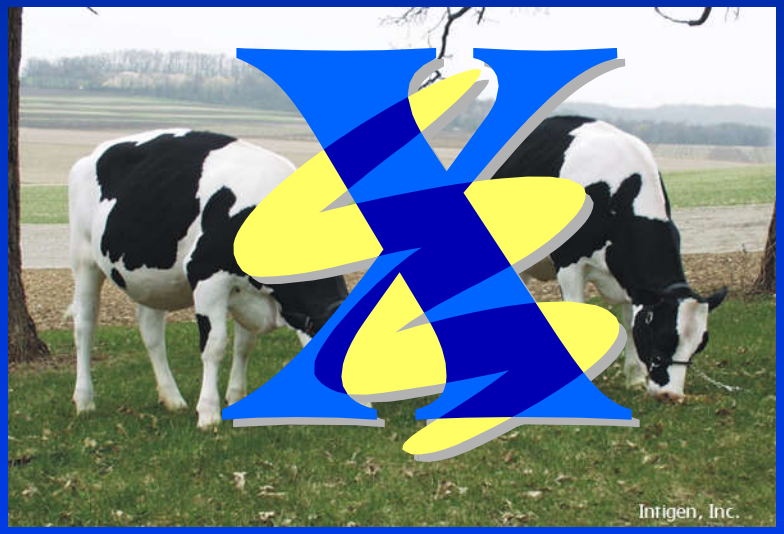
Why Interest in Genetic Engineering in Animals?

- Technology is Accessible to Small Companies & Labs Worldwide = Here to Stay
- An Alternative to Antibiotics and Steroid Hormones In Feed, Implants, etc.
- Agricultural and Medical Approaches in Many Animal Species

Genetically Engineered Salmon : Ag-Biotech



Biopharming

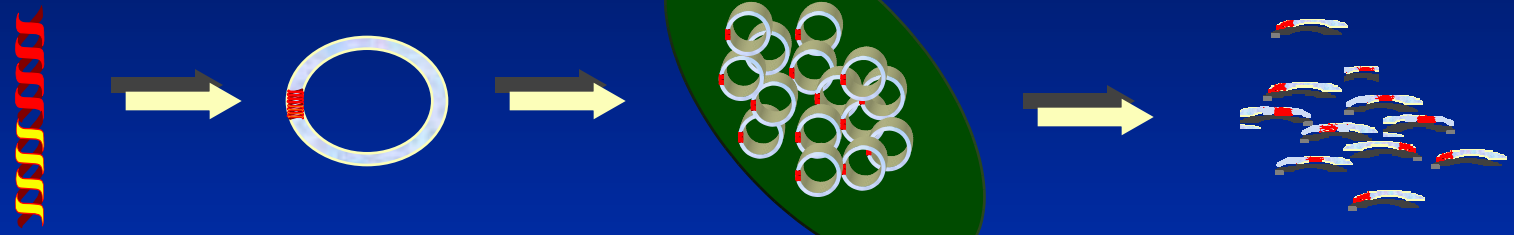


Clones

Ag-Biotech Examples

- Growth-Enhanced Atlantic Salmon
- Enviro-Pig – Low Phosphorus Wastes
- Mastitis-Resistant Dairy Cows
- Double Muscled Poultry
- BSE-Resistant Cattle
- Cows Producing Milk with Long Shelf Life
- Hypo-Allergenic Cat
- Glo-Fish

Producing A Line of Transgenic Fish



Gene Construct

Plasmid

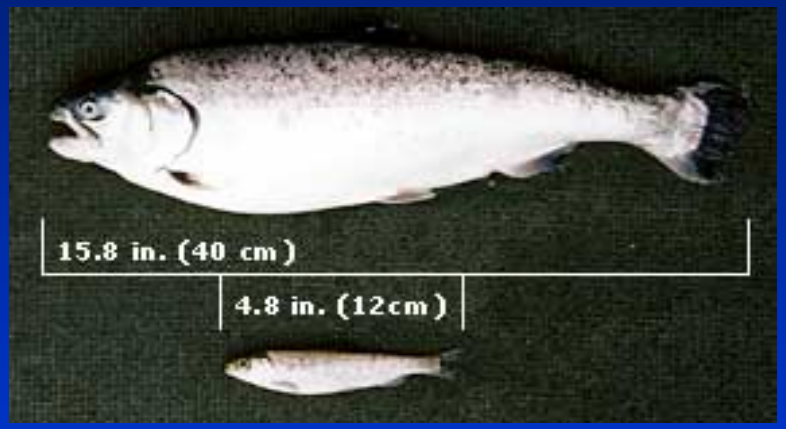
Bacterial Culture

Gene Cassettes

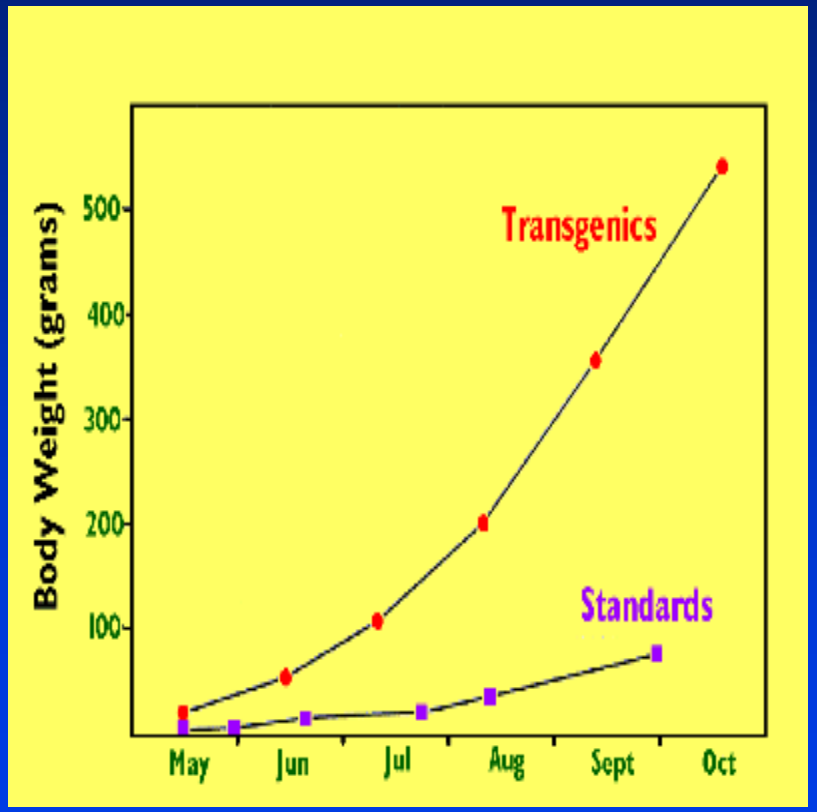
2 Million Cassettes/Egg

Mixed Transgenic Population

Growth Hormone-Enhanced Atlantic Salmon



These salmon are the same age, yet one grew spectacularly, thanks to a gene transplant



New Animal Productivity Tools

Defective Myostatin Gene Regulation =

Double Muscled Poultry

Biopharming

Drugs, Biologics, Industrial Substances
Harvested from Milk of Goats and Cattle

Biopharming Also Generates

- Up to 3/4 of Offspring are Excess Transgenic and Normal Calves and Kids
- Culled Surrogate Mothers and Egg Donors
- Culled Transgenic Production Animals
- “No-Takes” and Mosaics
- Milk By-Products

Pre-requisites for Success of Animal Biotech

- Products that Consumers AND Farmers and Ranchers Desire
- Science-Based Regulatory Process
- Credibility with the Public and Trading Partners
- Clear Communication of Approval Requirements

Where are We Now?

- OSTP Case Studies Contained the FDA Legal Interpretation on Ag-Biotech & Biopharm Animals - December 2000
- Coordinated Framework for Animal Biotech Still under Deliberation at OSTP level
- CVM Process Continues in lieu of Further Policy Announcements

CVM's Process Derives from Regulation of New Animal Drugs

- Controls over Investigations
- Pre-Market Approval Process
- Addresses Safety and Effectiveness
- Post-Market Reporting
- Addresses Imports of Foods Derived from Ag-Biotech Animals
- Documentation of Decisions

May 13, 2003 CVM Open Letter to Land Grant University Presidents

"This letter serves to remind those involved in research involving genetic engineering in animal species commonly used for food that such research may require an investigational new animal drug exemption (INAD) or another type of regulatory approval from the Center for Veterinary Medicine (CVM), FDA. See 21 CFR 511.1(b). FDA also expects documentation of plans regarding the disposition of all investigational animals after their participation in the study is completed."

CVM's Public Health Objectives for Animal Biotechnology

- Food and Feed Safety first
- Knowledge of "What's going on?"
- Proactive rather than Reactive
- Safe and responsible development of the many new products possible through animal biotechnology

Investigations

- Basic Research – Under NIH Guidelines, Animal Welfare Act, etc.
- Product Development – Under Investigational Files (INADs) at CVM
  - Animal Disposition – all means in food-producing species but especially request for rendering or food use
  - Development of Safety and Effectiveness Data in Support of Commercial Approval

Why an INAD File?

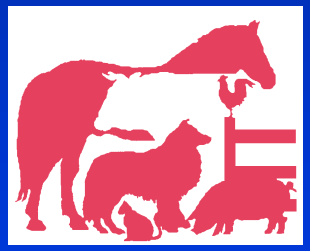
- Not always - sometimes a regulatory discretion letter will do
- INAD is the instrument that we have available to make food and feed disposition authorizations
- Using the INAD file for now, eventually may customize something better

Enforcement Discretion

- Limited Situations
- Not An Approval, Can Be Revoked Quickly if Situation Changes
- Examples include Transgenic Laboratory Animals, Glo-Fish

More to Do

- Federal Statement of Policy
- Regulations & Guidances Specific for Animal Biotech Product Groupings
- More Communication with the Public
- Harmonization with Trading Partners – OECD and Codex Alimentarius



CVM's Web Site is:
www.fda.gov/cvm
See CVM's Biotechnology Page